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MAY 4 2006

510(k) SUMMARY

RC Loop Anchor with Dual Orthocord Suture

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767
Contact Person	Kristine Christo Senior Regulatory Affairs Specialist DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Telephone: 508-828-3359 Facsimile: 508-977-6955 e-mail: KChristo@Dpyus.jnj.com
Name of Medical Device	Classification Name: Screw, Fixation, Bone Staple Common/Usual Name: Appliance for reconstruction of soft tissue to bone Proprietary Name: RC Loop Anchor
Substantial Equivalence	RC Loop Anchor is substantially equivalent to: Panalok RC Loop Anchor, K041065, manufactured by DePuy Mitek.
Device Classification	Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Single/Multiple component metallic bone fixation appliances and accessories. RC Loop Anchor Systems carry FDA product code JDR and is classified assingle / multiple component metallic bone fixation appliances and accessories soft tissue fastener under 21 CFR 888.3030.
Device Description	RC Loop with Dual Suture is a preloaded, absorbable disposable suture anchor/ inserter assembly for rotator cuff repair. The absorbable polylactic acid (PLA) anchor is an identical anchor as that of the Panalok RC Loop Anchor in design and configuration. The absorbable anchor is a one piece suture anchor constructed of molded Poly (L-

	lactide) polymer. The anchor system may be sold with Ethibond Suture (NDA 17-804 and 17-809), Panacryl Suture (K964345), or Orthocord Suture (K040004 and K043298).
Indications for Use	The RC Loop Anchor with Dual Orthobond Suture is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows: Rotator cuff repair
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the ORTHOCORD suture conformed to the USP monograph for absorbable sutures, and the suture compatibility and deployment met predetermined acceptance criteria. Based on the indications for use, technological characteristics, and comparison to predicate devices, the RC Loop Anchor with Dual Orthocord Suture has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 4 2006

Depuy Mitek
a Johnson & Johnson Company
% Ms. Kristine Christo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K060553
Trade/Device Name: RC Loop Anchor with Dual Orthocord Suture
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: April 10, 2006
Received: April 11, 2006

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060553

Device Names: RC Loop Anchor with Dual Orthocord Suture

Indications for Use:

The RC Loop Anchor with Dual Orthocord Suture is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

Rotator cuff repair

Prescription Use ___√___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert Lerner MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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